

Message

From: Ziegler, Rick [Ziegler.Rick@epa.gov]
Sent: 6/20/2017 7:05:15 PM
To: Smith, Walker [Smith.Walker@epa.gov]; Ferrante, Joe [Ferrante.Joe@epa.gov]
Subject: OECD, EPA and U.S. value example

Hi Joe and Walker,

Thought I'd share this recent example of a positive intersection among OECD, EPA and US industry. State Dept has been driving home the importance of this intersection with me at the margins of various meetings. The two most recent e-mails immediately below provide the gist:

From: O'Keeffe, Thomas A [mailto:OKeeffeTA@state.gov]
Sent: Tuesday, June 20, 2017 1:57 PM
To: Liem, Francisca <Liem.Francisca@epa.gov>
Cc: Ziegler, Rick <Ziegler.Rick@epa.gov>; Vaughn, Seth H <VaughnSH@state.gov>; Gabor, Robert R <GaborRR@state.gov>
Subject: RE: E-Introduction on GLP Issues

F--

This is very helpful. It sounds like EPA was able to tell CropLife there's already been substantial collaboration and direct benefits to industry. I am glad that you met them-- it's very important, especially now, that we engage stakeholders, show what we do for them and that we are ready to hear their concerns.

--T

SBU
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From: Liem, Francisca [mailto:Liem.Francisca@epa.gov]
Sent: Tuesday, June 20, 2017 11:58 AM
To: O'Keeffe, Thomas A
Cc: Ziegler, Rick
Subject: RE: E-Introduction on GLP Issues

Hi Thomas,

I spoke with Ray McAllister, Senior Director, Regulatory Affairs of CropLife America. Jane Collins was briefly on the phone.

Ray would like to know the status of China applying to OECD Mutual Acceptance of Data (MAD) System. I explained that China has not applied. OECD is revising their requirements, so that it will be easier for China and other countries to apply. We were also discussing the collaboration between EPA and China Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA). EPA has been working with China on GLP since 2005 and signed a Letter of Intent in 2005, and renewed every two years. In 2013 a new Letter of Intent was signed. The intentions of the 2013 LOI between EPA and China ICAMA includes:

- Reciprocal recognition of each Party's GLP program; and
- Procedures between the Parties for continued cooperation, intended to lead to mutual acceptance of data for review and consideration.

The reciprocal recognition of ICAMA and EPA GLP programs and mutual acceptance of data will benefit EPA and the US pesticide industry:

1. EPA does not need to do its own inspections of Chinese laboratories, but can rely on ICAMA to do so. This will save EPA resources.
2. US pesticide companies do not have to do the generation of data to support their product approval in China, as required by Chinese law. The data can be generated by US laboratories. This will save US companies financial resources.
3. US laboratories will benefit from the reciprocal recognition which generates jobs for US scientists.

CropLife America recommended for EPA to keep collaborating with China ICAMA and working with OECD in its efforts to expedite China's application to OECD MAD program.

Please let me know if you have questions.

Best regards,

Francisca Liem
 Director, Good Laboratory Practice (GLP) Program
 202-564-4148
Liem.francisca@epa.gov

On May 25, 2017, at 3:50 PM, O'Keeffe, Thomas A <OKeeffeTA@state.gov> wrote:

Dear Janet and Francisca,

I want to introduce you both. Francisca, Dr. Janet Collins is CropLife's Sr. VP for Science and Regulatory Affairs. She's reached out to us in advance of the June 26-30 meetings of the OECD Working Party on Pesticides, and hopes to discuss with you whether you see potentially unhelpful items migrating from the EU or CODEX into the OECD's Good Laboratory Practices. Janet is here in DC at Ex. 6 Personal Privacy (PP).

Janet, Francisca is the Director of EPA's Good Laboratory Practice (GLP) program and represents the U.S. at the OECD GLP Working Group. She has worked with CropLife America (CLA) as one of the GLP program's stakeholders. I hope you'll both connect soon on the nexus between OECD and EPA GLPs. Francisca will be out of the office starting tomorrow and return on June 6, but she can be reached by email.

Please both let me know if you need anything else.

--T

T.A. O'Keeffe
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 Bureau of Economic and Business Affairs, U.S. Department of State
 (202) 647-0286 (office), (202) 550-3317 (cell)

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From: Liem, Francisca [<mailto:Liem.Francisca@epa.gov>]
Sent: Thursday, May 25, 2017 3:01 PM
To: Ziegler, Rick; O'Keeffe, Thomas A
Cc: Vaughn, Seth H; Yun, Sara S; Pascual, Michael T; Gabor, Robert R; Barkas, Jessica; Goodis, Michael; Ferrante, Joe
Subject: RE: Chemicals Committee Q

Hello Everyone,

I am the Director of EPA's Good Laboratory Practice (GLP) program and represent the US at the OECD GLP Working Group. We have worked with CropLife America (CLA), they are one of the GLP program's stakeholders. CLA may contact me regarding the OECD and EPA GLPs if they have questions.

Tom, I will be out of the office starting tomorrow, and return on June 6. Let me know if I can be of any help.

Wishing you all a good Memorial Day weekend.

Francisca Liem

From: Ziegler, Rick
Sent: Thursday, May 25, 2017 2:41 PM
To: O'Keeffe, Thomas A <OKeeffeTA@state.gov>
Cc: Vaughn, Seth H <VaughnSH@state.gov>; Yun, Sara S <YunSS2@state.gov>; Pascual, Michael T <PascualMT@state.gov>; Gabor, Robert R <GaborRR@state.gov>; Barkas, Jessica <barkas.jessica@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Liem, Francisca <Liem.Francisca@epa.gov>; Ferrante, Joe <Ferrante.Joe@epa.gov>
Subject: RE: Chemicals Committee Q

Hi Tom,

Let me introduce a few folks who might be the right points of contact. And if not, I suspect this cc'd group can help us find the right path.

Francis Liem (cc'd) is an EPA point of contact for the Working Party on GLPs.
Michael Goodis (cc'd) I believe is an EPA point of contact for the Working Party on Pesticides.
Jessica Barkas is an EPA POC for the Chemicals Committee.

I will be headed out of the office for the weekend in the next few minutes, and I think Michael is also out until after the holiday (returning back May 30). Though, I do not want to slow this down. I'm not familiar with CropLife [yet], but I'm interested in seeing how this plays out and how we can be helpful.

Rick
202-564-2231

From: O'Keeffe, Thomas A [<mailto:OKeeffeTA@state.gov>]
Sent: Wednesday, May 24, 2017 3:34 PM
To: Ziegler, Rick <Ziegler.Rick@epa.gov>
Cc: Vaughn, Seth H <VaughnSH@state.gov>; Yun, Sara S <YunSS2@state.gov>; Pascual, Michael T <PascualMT@state.gov>; Gabor, Robert R <GaborRR@state.gov>
Subject: RE: Chemicals Committee Q

R--

Nice to see you yesterday. What's your phone number? Somehow I don't have it where I need it.

I just got off the phone with Dr. Janet Collins of CropLife who wants to speak with the head of Del for the OECD Environment Committee's Working Party on Pesticides, which meets in Paris next June 26-30. She wants to discuss OECD's Good Laboratory Practices (GLP) guidelines, with a concern to make sure that they are aligned with EPA's GLP. She says tweaks originating in the EU or CODEX will often be slipped in here and there that can be outdated or problematic.

CropLife signed on to the EAGL Coalition of companies, organized by the National Association of Manufacturers (NAM) that is calling for an improved interface between U.S. business and other stakeholders and multilateral organizations that make rules affecting them. We want to be responsive.

Can you let me know soonest who the head of Del might be, or to whom she might speak?

Gracias!

--T

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T.A. O'Keeffe
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